

**Final Statement of Reasons for the Adoption of the  
Proposed Amendments to California Code of Regulations,  
Title 18, Section 1591, *Medicines and Medical Devices***

Update of Information in the Initial Statement of Reasons

The State Board of Equalization (Board) held a public hearing regarding the proposed amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*, on April 28, 2015. During the public hearing, the Board unanimously voted to adopt the proposed amendments to Regulation 1591 without making any changes. The Board did not receive any written comments regarding the proposed regulatory action and no interested parties appeared at the public hearing on April 28, 2015, to comment on the proposed regulatory action.

The factual basis, specific purpose, and necessity for, the problem to be addressed by, and the anticipated benefits from the adoption of the proposed amendments to Regulation 1591 are the same as provided in the initial statement of reasons. The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by Revenue and Taxation Code section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The adoption of the proposed amendments to Regulation 1591 is not mandated by federal law or regulations. There is no previously adopted or amended federal regulation that is identical to Regulation 1591 or the proposed amendments to Regulation 1591.

The Board did not rely on any data or any technical, theoretical, or empirical study, report, or similar document in proposing or adopting the proposed amendments to Regulation 1591 that was not identified in the initial statement of reasons, or which was otherwise not identified or made available for public review prior to the close of the public comment period.

In addition, the factual basis has not changed for the Board's initial determination that the proposed regulatory action will not have a significant adverse economic impact on business, the Board's determination that the proposed regulatory action is not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000, and the Board's economic impact assessment, which determined that the Board's proposed regulatory action:

- Will neither create nor eliminate jobs in the State of California;
- Nor result in the elimination of existing businesses;
- Nor create or expand business in the State of California; and

- Will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

The proposed amendments to Regulation 1591 may affect small business.

#### No Mandate on Local Agencies or School Districts

The Board has determined that the adoption of the proposed amendments to Regulation 1591 does not impose a mandate on local agencies or school districts.

#### No Public Comments

The Board did not receive any written comments regarding the proposed regulatory action and no interested parties appeared at the public hearing on April 28, 2015, to comment on the proposed regulatory action.

#### Determinations Regarding Alternatives

By its motion on April 28, 2015, the Board determined that no alternative to the proposed amendments to Regulation 1591 would be more effective in carrying out the purpose for which the amendments are proposed, would be as effective and less burdensome to affected private persons than the adopted amendments, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

The Board did not reject any reasonable alternatives to the proposed amendments to Regulation 1591 that would lessen any adverse impact the proposed amendments may have on small business.

No reasonable alternatives have been identified and brought to the Board's attention that would lessen any adverse impact the proposed action may have on small business, be more effective in carrying out the purposes for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.